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08/420,503	04/12/95	QUINN	M 4544-011-25-

33M1/0215
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NASSER, EXAMINER

ART UNIT	PAPER NUMBER
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3311

DATE MAILED: 02/15/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 45-58 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 45-54 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The examiner acknowledges applicant's request under 37 C.F.R. § 1.607 to provoke an interference with U.S. patent number 5,435,308. However, because of the problems with the application, the interference has not been set up by the examiner.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the claimed invention. Throughout the claims, applicant has referred to the working length of the multi-lumen main body portion. However, such term has not been defined in the specification. Therefore, it is unclear what applicant is referring to. For the purposes of any art rejection, the examiner has interpreted the term working length to mean the entire length of the multi-lumen main body portion. Also, in claim 53, applicant discusses making fluid injectate thermodilution measurements. However, the present invention introduces heat into the bloodstream and measures the resulting temperature change to determine cardiac output. Therefore, it is

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unclear how the injectate lumen enables thermodilution measurements, as the present invention does not make bolus injectate measurements.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing the disclosure, as originally filed, fails to provide support for the invention, as now claimed. Specifically, in claims 45, 57, and 58, in paragraph d(v), applicant recites that the device includes a fiber optic apparatus, including filaments disposed in the lumen, extending the working length of the multi-lumen main body portion into a fiber optic coupler. This has no basis in the specification, as all applicant has disclosed is that one of the lumens may receive a module for determining mixed venous oxygen saturation including a fiber optic bundle. This does not provide support for the filaments extending the working length of the multi-lumen main body portion, or for the fiber optic coupler that is associated with the catheter. Hence, both limitations introduce new matter. In addition, in paragraph f, applicant has recited that wiring extends the entire working length of the multi-lumen main body portion. This limitation introduces new matter, as the specification does not provide support for any wiring extending the working length of the catheter. The examiner notes that if applicant amended the claim to recite that the wiring extended from the temperature measuring apparatus, along the length of the

multi-lumen main body portion to a housing ..., it would overcome this rejection. In claim 47, applicant has recited that the necked down portion is 5-10 centimeters in length. Applicant points to page 18, lines 22-24 and page 22, lines 3-7 as providing support for these limitations. It is the examiner's position that the enumerated pages merely state that the heating filament is 5-10 cm long. No teaching of the length of the necked down portion is provided in applicant's specification. Hence, claim 47 introduces new matter, as nowhere does applicant state that the heating filament and the necked down portion are the same length. Further, in claim 49, applicant has recited that the temperature measurement apparatus comprises a thermistor which is adjacent the distal end of the heater coil. The examiner notes that this limitation has no support in the specification, as the thermistor is disclosed as being 1-2 cm from the distal end, while the heater coil is disclosed as being 14-15 cm from the distal end. Hence, the thermistor and heater coil are approximately 12-13 cm apart, which are not "adjacent". Hence, this claim introduces new matter. In claim 53 and 58, applicant recites that the injectate lumen allows injectate fluid to be injected into the blood stream to enable thermodilution measurements. While there is basis for the lumen allowing for proximal fluid infusion, there is no antecedent basis in the specification for fluid injection thermodilution

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measurements. On pages 27-28, applicant states that the co-pending McKown et al application, now US Patent 5,146,414 discusses fluid injection thermodilution, nowhere does applicant state that such fluid injectate thermodilution measurements are used with the present invention. Therefore, claims 53 and 58 introduce new matter.

Claims 45-58 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 46-53, 57, and 58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46 and 57 are rejected as duplicates of each other. Claims 53 and 58 are rejected as being substantial duplicates. In both cases, the dependent claims from 45, 46 and 53, recite the features that distinguish claims 57 and 58 from the claim 45. Hence, the claims duplicate each other. Claims 47-52 are rejected as being dependent on a rejected base claim. Clarification is required.

Claims 45-58 define over the art of record. However, if applicant were to amend the claim to state that wiring extends from the thermistor, along the working length of the catheter to a housing at the end, the examiner notes that claim 45, 53, 54, and 56-58 would then be rejected over Willis in view of Khalil

and Claim 55 would be rejected over Willis in view of Khalil and Grise. Willis shows all of the features of the claims except that it measures cardiac output using a cold bolus injection. Khalil teaches that cold bolus injections and using external heaters heat the blood are equivalent methods of measuring cardiac output. Further Grise teaches that a substrate based heater is an improvement over a single wire of Khalil. Therefore, applicant should consider this combination when responding to this action.

The examiner notes that the original claims in the application 07/914279 were rejected under an equivalent combination as that shown above, and the claims were amended to overcome the rejection. Hence, the present claims are broader than the patented claims and the ground of rejection above would not be applicable to the patented claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Moran shows a multi-lumen catheter that measures blood oxygen levels. It does not also make cardiac output measurements.

Williams et al shows a multi-lumen catheter.

Willis, Khalil, and Grise have been discussed above.

Gallup et al is the patent applicant attempted to provoke an interference with.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Nasser whose telephone number is (703) 308-3251.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Robert S. Nasser J.

RLN

February 3, 1996